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PATENT  
DOCKET NO. BSA-010.03

In re Application of: Babich, J.W., et al.

Application No: 10/756,793

Filed: January 13, 2004

For: Imaging Agents for Diagnosis of  
Parkinson's Disease

Art Unit: 1625

Examiner: Not Yet Known

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on *July 7, 2004*

  
John Barretto

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Forms PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Under 35 U.S.C. §120, this application has the benefit of the filing date of U.S. Patent Application 10/352,764, filed January 28, 2003, now US Patent 6,677,454; and US Patent Application 09/790,320 filed February 22, 2001, now US Patent 6,515,131. Copies of references AA-CU listed on the Forms PTO-1449 were submitted to the Office in the parent applications; therefore, they are not required to be provided in this application.

**REMARKS**

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed:

(1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office Action** on the merits, or before the mailing of a **first Office Action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or

(2) after the period defined in (1) but before the mailing date of a **final action or a notice of allowance** under 37 C.F.R. 1.311, and

the requisite Statement is below, **OR**

the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or

(3) after the mailing date of a **final action or notice of allowance** but before the payment of the **issue fee**, **AND**

the requisite Statement is below, **AND**

the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

## STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that **[check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]**:

- 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
  
- 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Respectfully submitted,



Date: July 7, 2004  
Reg. No. 44,719

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Form PTO-1449 <b>INFORMATION DISCLOSURE CITATION</b> <b>IN AN APPLICATION</b> (Use several sheets if necessary)			Docket Number (Optional) BSA-010.03 (20704-1002)		Application Number 10/756,793	
			Applicant Babich, J.W et al.			
			Filing Date January, 13, 2004		Group Art Unit 1625	

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PARENT &amp; TRADEMARKS

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER		DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA US 5,288,514		02/22/94	Ellman	427	2	09/14/92
	AB US 5,362,899		11/08/94	Campbell	558	108	09/09/93
	AC US 5,359,115		10/25/94	Campbell et al.	558	110	09/11/92
	AD US 5,143,854		09/01/92	Pirrung et al	436	518	03/07/90
	AE US 5,480,971		01/02/96	Houghten et al.	530	328	06/09/94
	AF US 5,440,016		08/08/95	Blondelle et al	530	330	06/18/93
	AG US 5,919,934		01-2001	John et al	546	247	
	AH US 6,171,576		01-2001	Meltzer et al.	424	1.65	
	AI US 5,136,038		08-1992	Bodor	546	169	

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						YES	NO
	AJ WO 91/07087	05/30/91	PCT				X
	AK WO 93/09668	05/27/93	PCT				X
	AL WO 92/10092	06/25/92	PCT				X
	AM WO 94/08051	04/14/94	PCT				X
	AN WO 93/20242	10/14/93	PCT				X
	AO WO 98/37055	08/27/98	PCT				X
	AP WO 01/83436 A2	11/08/01	PCT				X
	AQ WO 01/98266	12-2001	PCT				
	AR EP 0 200 211 A1	11/05/86	European Patent Application				X

**OTHER DOCUMENTS***(Including Author, Title, Date, Pertinent Pages Etc.)*

AS	Innis et al.; "Single Photon Emission Computed Tomography Imaging of Monoamine Reuptake Sites in Primate Brain With [ <sup>123</sup> I] CIT", European Journal of Pharmacology 200, 369-370, (1991)
AT	Kung et al.; "Imagine of Dopamine Transporters in Humans with Technetium-99m TRODAT-1", European Journal of Nuclear Medicine, 23 (11): 1527-1530, (1996)
AU	Dahl et al.; "Deletion Mapping of X-Linked Mixed Deafness (DFN3) Identifies A 265-525-kb Region Centrometric of DDX26", Am. J. Hum. Genet. 56: 999-1002, (1995)
AV	Valerio et al.; "Synthesis of Peptide analogues Using the Multiplin Peptide Synthesis Method", Analytical Biochemistry 197: 168-177 (1991)

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AW	Stoof et al.; "Leads for the Development of Neuroprotective Treatment in Parkinson's Disease and Brain Imaging Methods for Estimating Treatment Efficacy", European Journal Of Pharmacology 375: 75-86, (1999)		
AX	Gallop et al.; "Application of Combinatorial Technologies to Drug Discovery. 1. Background and Peptide Combinatorial Libraries", Journal of Medicinal Chemistry, 37(9) : 1233-1251, (April 29, 1994)		
AY	Berge et al.; "Pharmaceutical Salts", Journal of Pharmaceutical Sciences, 66(1): 1-19, (January 1977)		
AZ	Ohlmeyer et al.; "Complex Synthetic Chemical Libraries Indexed with Molecular Tags", Proc. Natl. Acad. Sci., USA, 90: 10922-10926, (December 1993)		
BA	Innis et al.; "Single Photon Emission Computed Tomographic Imaging Demonstrates Loss of Striatal Dopamine Transporters in Parkinson Disease", Proc. Natl. Acad. Sci. , USA 90: 11965-11969, (December 1993)		
BB	Kung et al.; "Synthesis of New Bis (Aminoethanethiol) (BAT) Derivatives: Possible Ligands for <sup>99m</sup> Tc Brain Imaging Agents", J. Med. Chem. 28: 1280-1284, (1985)		
BC	Meltzer et al.; "Substituted 3-Phenyltropane Analogs of Cocaine: Synthesis, Inhibition of Binding at Cocaine Recognition Sites, and Positron Emission Tomography Imaging", J.Med. Chem. 36: 855-862, (1993)		
BD	Carroll et al.; "Cocaine Receptor: Biochemical Characterization and Structure-Activity Relationships of Cocaine Analogues at the Dopamine Transporter", Journal of Medicinal Chemistry, 35(6): 969-981, (March 20, 1992)		
BE	Meegalla et al.; "First Example of a <sup>99m</sup> Tc Complex as a Dopamine Transporter Imaging Agent", J. Am. Chem. Soc. 117: 11037-11038, (1995)		
BF	Smith et al.; "Tuning Selectivity of Monoamine Transporter Inhibitors by the Stereochemistry of the Nitrogen Lone Pair", J. Am. Chem. Soc. 120: 9072-9073, 9 1998)		
BG	Neumeyer et al.; "[ <sup>123</sup> ]2β-Carbomethoxy-3β-(-(4-iodophenyl) Tropane: High-Affinity SPECT Radiotracer of Monoamine Reuptake Sites in Brain", J. Med. Chem. 34 : 3144-3146, (1991)		
BH	Hoepping et al.; "Synthesis and Biological Evaluation of Two Novel Dat-Binding Technetium Complexes Containing a Piperidine Based Analogue of Cocaine", Bioorganic & Medicinal Chemistry Letters, 9: 3211-3216, (1999)		
BI	Gu et al.; "Stable Expression of Biogenic Amine Transporters Reveals Differences in Inhibitor Sensitivity, Kinetics, and Ion Dependence", The Journal of Biological Chemistry, 269 (10): 7124-7130, (1994)		
BJ	Frost et al.; "Positron Emission Tomographic Imaging of the Dopamine Transporter with <sup>11</sup> C -WIN 35,428 Reveals Marked Declines in Mild Parkinson's Disease", Annals of Neurology, 34: 423-431, (1993)		
BK	Blaney and Dixon, "Receptor Modeling by Distance Geometry", Annual Reports in Medicinal Chemistry, 26:281-286, (1991)		
BL	Meegalla et al.; "Synthesis and Characterization of Technetium-99m- Labeled Tropanes as Dopamine Transporter-Imaging Agent", J. Med. Chem. 40: 9-17, (1997)		
BM	Hamilton and Steiner, "Immunophilins: Beyond Immunosuppression", Journal of Medicinal Chemistry, 41(26):5119-5143, (December 17, 1998)		

Form PTO-1449 <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b> <i>(Use several sheets if necessary)</i>		Docket Number (Optional) BSA-010.03 (20704-1002)		Application Number 10/756,793	
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BN	Luyt et al.; "An N <sub>2</sub> S <sub>2</sub> Bifunctional Chelator for Technetium-99m and Rhenium: Complexation, Conjugation, and Epimerization to a Single Isomer", <i>Bioconjugate Chem.</i> 10: 470-479, (1999)				
BO	Hom and katzenellenbogen; "Technetium-99m-Labeled Receptor-Specific Small-Molecule Radiopharmaceuticals: Recent Developments and Encouraging Results", <i>Nuclear Medicine and Biology</i> , 24: 485-498, (1997)				
BP	Nicholson et al.; "The Synthesis and Characterization of [MCl <sub>3</sub> (N=NC <sub>5</sub> H <sub>4</sub> NH) (HN=NC <sub>5</sub> H <sub>4</sub> N) ] From [MO <sub>4</sub> ] <sup>-</sup> (where M= Re, Tc) Organodiazenido, Organodiazene-Chelate Complexes. The X-ray Structure of [ReCl <sub>3</sub> (N=NC <sub>5</sub> H <sub>4</sub> NH) (HN=NC <sub>5</sub> H <sub>4</sub> N) ]", <i>Inorganica Chimica Acta</i> , 252: 421-426, (1996)				
BQ	Rose et al.; "Synthesis and Characterization of Organohydrazino Complexes of Technetium, Rhenium, and Molybdenum with the { M( <sup>1</sup> -H <sub>x</sub> NNR)( <sup>2</sup> -H <sub>y</sub> NNR) } Core and Their Relationship to Radiolabeled Organohydrazine-Derivatized Chemotactic Peptides With Diagnostic Applications", <i>Inorg. Chem.</i> 37: 2701-2716, (1998)				
BR	Fowler et al.; "Mapping Cocaine Binding Sites in Human and Baboon Brain In Vivo", <i>Synapse</i> , 4:371-377, (1989)				
BS	Villemagne et al.; "Doses of GBR12909 That Suppress Cocaine Self-Administration in Non - Human Primates Substantially Occupy Dopamine Transporters as Measured by [ <sup>11</sup> C ] WIN35,428 PET Scans", <i>Synapse</i> 32: 44-50, (1999)				
BT	Shaya et al.; "In Vivo Imaging of Dopamine Reuptake Sites in the Primate Brain Using Single Photon Emission Computed Tomography (SPECT) and Iodine-123 Labeled RTI-55", <i>Synapse</i> 10: 169-172 (1992).				
BU	Ilgin et al.; "PET Imaging of the Dopamine Transporter in Progressive Supranuclear Palsy and Parkinson's Disease", <i>Neurology</i> 52: 1221-1226, (1999)				
BV	Kaufman and Madras; "Distribution of Cocaine Recognition Sites in Monkey Brain: II. EX Vivo Autoradiography With [ <sup>3</sup> H] CFT and [ <sup>125</sup> I ] RTI-55", <i>Synapse</i> 12: 99-111, (1992).				
BW	Jacobs and Fodor, "Combinatorial Chemistry- Applications of Light-directed Chemical Synthesis", <i>TIBTECH</i> . 12:19-26, (January 1994).				
BX	Chen et al.; " "Analogous" Organic Synthesis of Small Compound Libraries: Validation of Combinatorial Chemistry in Small-Molecule Synthesis", <i>J. Am. Chem. Soc.</i> 116: 2661-2662, (1994)				
BY	Kerr et al.; "Encoded Combinatorial Peptide Libraries Containing Non- Natural Amino Acids", <i>J. Am. Chem. Soc.</i> 115: 2529-2531, (1993)				
BZ	Kozikowski et al ;" Chemistry and Pharmacology of the Piperidine-Based Analogs of Cocaine. Identification of Potent DAT Inhibitors Lacking the Propane Skeleton", <i>J. Med. Chem.</i> 41: 1962-1969, (1998)				
CA	Patane et al.; " Selective $\alpha$ - 1A Adrenergic Receptor Antagonists. Effects of Pharmacophore Regio-and Stereochemistry on Potency and Selectivity", <i>Bioorganic and Medicinal Chemistry Letters</i> 8:2595-2500, (1998)				
CB	Yung et al.; " In Vivo Dopamine Transporter Sites Imaging in Human Using [c-11] WIN 35,428 Positron Emission Tomography (pet)", <i>The Journal of Nuclear Medicine</i> , 34(5): 197P(Abstract book), ( May 1993)				
CC	Spies et al.; " Neutral Oxorhenium (v) Complexes with Tridentate Dithiolates and Monodentate Alkane- or Arene-thiolate Coligands", <i>J. Chem Soc. Dalton Trans.</i> ; No 13, pp.2277-2280, (July 7 <sup>th</sup> , 1995 )				
CD	Needels et al.; "Generation and Screening of an Oligonucleotide-encoded synthetic Peptide Library", <i>Proc. Natl. Acad. Sci. USA</i> 90: 10700-10704, (November 1993)				

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	CE	Brenner and Lemner, "Encoded Combinatorial Chemistry", Proc. Natl. Acad. Sci. USA 89: 5381-5383, (June 1992 )			
	CF	Bray et al.; " Gas Phase Cleavage of Peptides from a Solid Support with Ammonia Vapour. Application in Simultaneous Multiple Peptide Synthesis", tetrahedron Letters 32(43): 6163-6166, (1991)			
	CG	Bray et al.; " The Simultaneous Multiple Production of Solution Phase Peptides; Assessment of the Geysen Method of Simultaneous Peptide Synthesis", Tetrahedron Letters, 31 (40): 5811-5814, (September 24, 1990)			
	CH	Pátek and Lebl, " Safety-Catch anchoring Linkage for Synthesis of Peptide Amides by Boc/Fmoc Strategy", Tetrahedron Letters, 32 (31): 3891-3894 (July 29, 1991)			
	CI	Mitra-Kirtley; " Determination of the Nitrogen Chemical Structures in Petroleum Asphaltenes Using XANES Spectroscopy", J. Am Chem. Soc. 115(1): 252-258, (January 13, 1993 )			
	CJ	Geysen et al.; " Use of Peptide Synthesis to Probe Viral Antigens for Epitopes to a Resolution of a Single Amino Acid", Proc. Natl. Acad. Sci. USA 81(13): 3998-4002, (July 1984)			
	CK	Houghten A. Richard, " General Method for the Rapid Solid-Phase Synthesis of Large Numbers of Peptides: Specificity of Antigen-Antibody Interaction at the Level of Individual Amino Acids", Proc. Natl. Acad. Sci. , 82: 5131-5135, (August 1985 )			
	CL	Hui et al.; " Analysis of the Quantitative Structure Activity Relationship of Technetium-99m-Labeled Diaminedithiol (DADT) and Propyleneamineoxine (PAO) Brain Blood Flow Analogues", Appl. Radiat. Isot. (International Journal of Radiation Applications: Part A). 42(6): 503-508, (1991)			
	CM	Fodor et al.; " Light-Directed, Spatially Addressable Parallel Chemical Synthesis", Science, 251: 767-773, (February 15, 1991 )			
	CN	Galli et al.; " Sodium- Dependent Norepinephrine-Induced Currents in Norepinephrine-Transporter-Transfected Hek-293 Cells Blocked by Cocaine and Antidepressants", The Journal of Experimental Biology, 198: 2197-2212, (1995)			
	CO	Warren et al.; " New Iodinated Phenyl Fatty Acids For Imaging Myocardial Metabolism", The Journal of Nuclear Medicine 27(6): abstract no. 258, (June 1986)			
	CP	Mozley et al.; " Dosimetry of an Iodine-123-Labeled Tropane to Image Dopamine Transporters", J. Nucl. Med. , 3791): 151-159, (January 1996)			
	CQ	Nestler et al.; " A General Method for Molecular Tagging of Encoded Combinatorial Chemistry Libraries", J. Org. Chem. 59(17): 4723-4724, (august 26, 1994)			
	CR	Burbbaum et al.; "A Paradigm for Drug Discovery Employing Encoded Combinatorial Libraries", Proc. Natl. Acad. Sci. USA, 92: 6027-6031, (June 1995)			
	CS	Efange et al.; " Synthesis and Biodistribution of 99 mTc -Labeled Piperidinyl bis (Aminoethanethiol) Complexes: Potential Brain Perfusion Imaging Agents for Single Photon Emission Computed Tomography", CA 108: 167266 (1988)			
	CT	Partial International Search Report Mailed on Marcyh 14, 2002			
	CU	International Search Report Completed on June 20, 2002 and Mailed July 7, 2002			
EXAMINER				DATE CONSIDERED	
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.					